

**REMARKS**

Applicants wish to thank the Examiner for taking the time to meet with applicant's representatives and one of the inventors, Dr. Richter, on February 16, 2005. The instant amendments to the claims were discussed during this meeting. Favorable consideration was reached.

Claims have been amended to be directed to "coronary stents" and specify a difference in "strut widths" within the stent. Further, "flexible spaces" have been amended to --flexible cells--, and "a plurality of enclosed flexible spaces" are amended to --uniform pattern of flexible cells--. Support for these amendments is found throughout the specification and drawings, for example, at page 8, lines 9-29; and Figures 3 through 15. No new matter has been added.

Claims 2, 4-5, 7, 9-10, 12-25, 27, 29-30, 31-41, 48 and 50-51 have been canceled without prejudice. Applicants reserve the right to file a continuing application to prosecute these canceled claims.

Claims 31-41 directed at multicellular stents were previously withdrawn due to a restriction requirement. Applicants request the Examiner reconsider this restriction requirement upon allowance of the claims.

Applicants believe that the application is in form for allowance and such allowance is respectfully requested. The claims as amended are clearly distinguishable from the references cited in the present office action as well as reference cited in previous office actions. For example, as in the previous office action, Berry (US 6,231,598) is clearly distinguishable from the present invention since Berry fails to teach or suggest a uniform pattern of flexible cells.

**1. Jayaraman '245 Neither Anticipates Nor Renders Obvious**

Claims 1-2, 4, 6-7, 11-12, 14, 16-17, 19, 42-47 and 50-51 have been rejected as being anticipated by or, in the alternative, obvious over U.S. 6, 162, 245 to Jayaraman (Jayaraman '245). We traverse the rejection. As explained hereafter, Applicants respectfully submit that the pending claims as presently amended are neither anticipated nor rendered obvious by Jayaraman '245.

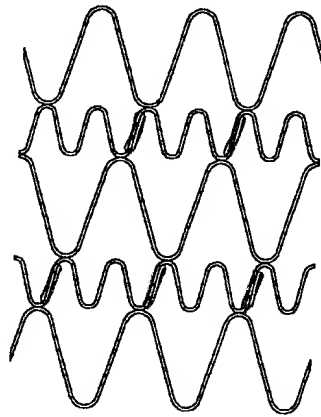
The Jayaraman reference does not teach or suggest the invention. In particular, the Jayaraman '245 reference fails to disclose at least the following features:

- (1) use of the stent design as a *coronary* stent,
- (2) differences in *strut width*,
- (3) loops 180 degrees out of phase, and
- (4) uniform patterns of flexible cells and functional limitations recited in the claim.

First, the Jayaraman reference does not disclose use of the stent design as a *coronary* stent. Jayaraman is directed at a vascular graft and replacement valve. (See Col. 1, lines 25-60). Second, the Jayaraman reference fails to disclose struts of different widths. In fact, Jayaraman teaches away from strut width difference by illustrating in the drawings embodiments of uniform strut width. Third, the Jayaraman reference does not teach or suggest loops 180 degrees out of phase along the longitudinal axis. As indicated by the present Office Action in Fig. 30 from the Jayaraman reference, loops are not out of phase along a longitudinal axis as is claimed. Notice that the peaks from adjacent loops in Jayaraman do not align. Finally, the Jayaraman reference does not teach or suggest uniform patterns of flexible cells

resulting in a more constant stent cell area on the inside and the outside of the curve of the stent.

Also note, the Jayaraman reference teaches a non-flexible stent. The reference teaches straight connectors between loop containing sections to form a rigid, non-flexible stent. (See Fig. 30).



*Fig. 30*

As can be seen above, the colored stent is not flexible because it does not contain any stored length, hence it is not flexible.

In addition, as discussed at the interview, the Jayaraman stent is not, in fact, a stent at all, but rather a scaffolding which is attached to a graft material. This feature is illustrated on inter alia in Figures 26-29 and 31. In these figures, one can see that the tops and bottoms of the loops of the Jayaraman structure are fastened to the graft material. Therefore, upon expansion, there can be no movement of these loops without tearing or otherwise damaging the graft material. This is quite in contrast to the flexible nature of the instant invention.

Further, the “3<sup>rd</sup> loop containing section/2<sup>nd</sup> circumferential band of a 2<sup>nd</sup> frequency,” as seen in Figure 30 (as characterized in the pending Official Communication) actually contributes more rigidity to the stent and is less flexible than the low frequency loops. The higher frequency sections, as seen in Jayaraman Fig. 30, are more rigid than the lower frequency sections because there is more material per unit area of stent in these high frequency sections (See Fig. 30, Jayaraman). This is distinguishable from the claimed invention in that the lower frequency circumferential band of the instant stent has wider struts than the struts of the high frequency bands, making the high frequency bands more flexible than low frequency. Nothing in the Jayaraman reference teaches or suggests that the higher frequency sections can provide the flexibility to the structure. Thus, Figure 30 of the Jayaraman reference does not teach or suggest the requirements of these claims.

Reconsideration and withdrawal of the rejections is respectfully requested.

## **2. Brown Neither Anticipates Nor Renders Obvious**

Claims 21-22, 24, 26-27, 29, and 48-49 have been rejected as anticipated by or in the alternative obvious over Brown et. al. (WO 00/30563 or US 20022007212 A1). Applicants respectfully traverse with this rejection.

Brown’s application fails to teach or suggest the use of struts of different widths in a stent. Brown requires every embodiment of uniform strut width.

Brown does not teach or suggest lower frequency loops which are 180° out of phase with adjacent low frequency loops along the longitudinal axis of the stent.

As shown in Brown, and in the Brown figure reproduced in the present Office Action, it is clear that these patterns are not 180° out of phase with each other.

Furthermore, there is no suggestion in Brown to modify their structures to reach the invention as recited in the claims.

Furthermore, as discussed during the interview with the Examiner, Brown does not teach or suggest a coronary stent. For Brown to teach a coronary stent, the number of loops per cell would need to be much smaller than that disclosed in Brown. As described in this publication, Brown has large cells in 3:5 ratio of loops. In order for this stent to be uniformly flexible, as claimed, it would need to have at least 3 connecting struts; hence a loop ratio of 9:15 around the circumference of the stent. Fifteen loops are equal to 30 struts which create too much bulk to be crimpable into a diameter small enough to fit into a coronary vessel. The large stent diameter of Brown results in a stent which can not be used as a coronary stent because it can not be sufficiently crimped.

For at least these reasons, reconsideration and withdrawal of the rejections is respectfully requested.

### **3. Jayaraman in View of Yang**

Claims 3, 5, 13, 15, 18, and 20 have been rejected as obvious under 35 U.S.C. §103(a) over Jayaraman in view of Yang (U.S. 6,120,847). Applicants respectfully disagree with this rejection.

The Examiner acknowledges that Jayaraman does not disclose a stent coated with medicine. As discussed above, Jayaraman does not teach or suggest the claimed stent. Jayaraman does not teach or suggest a stent wherein the high frequency loops contribute more to elongating, shortening and deformation than the low frequency loops, as claimed. Jayaraman does not teach or suggest a stent having loop containing sections or loops that are 180° out of phase with adjacent first and second loop

containing sections along the longitudinal axis of the stent, as recited in the claims.

Yang does not remedy these deficiencies.

Yang discloses surface treatments that eliminate surface imperfections on a medical device having a drug release coating. Yang eliminates these imperfections by a dipping or spraying process using a solvent carrier to incorporate a therapeutic agent within a polymer matrix.

The combination of Jayaraman with Yang does not render obvious a stent having a coating as recited in the claims. One skilled in the art reading these references would not be led to the instant invention, because neither Jayaraman nor Yang teach or suggest the basic stent design of the present invention.

The present invention provides a structure which more evenly contacts a vessel wall so as to provide an even distribution of medicine to a vessel wall. Nothing in Yang alone or in combination with Jayaraman teaches or suggests such a concept. Yang does not teach or suggest using the claimed stent design to provide for a more even dose being applied to the inside wall of a bodily lumen.

Because Jayaraman in view of Yang does not teach or suggest the claimed stent structure or the use of stent structure to provide an even distribution of medicine to a vessel wall, applicants assert that these references alone or in combination do not anticipate or render the claims obvious.

Reconsideration and withdrawal of the rejections is respectfully requested.

#### **4. Brown in View of Yang**

Claims 23, 25, 28 and 30 have been rejected as being obvious under 35 U.S.C. §103(a) over Brown in view of Yang. We respectfully traverse this rejection.

As discussed in detail above, Brown does not teach or suggest a stent structure having low frequency loops which are 180° out of phase with each other. Brown does not teach or suggest a stent useful in coronary arteries. Brown does not teach or suggest different strut width to allow enhanced flexibility as claimed. Therefore, Brown does not teach or suggest the claimed stent structure limitations of the claims.

Brown, when combined with Yang does not make the claims obvious. Yang describes using a surface treatment to provide a smooth surface for medicine. Yang does not teach or suggest using the stent structure itself to accomplish uniform dosage application to the vessel wall. Therefore, neither Brown alone or in combination with Yang teaches or suggests a stent structure as claimed or the use of a structure to produce a more uniform distribution of medicine on a vessel wall. Reconsideration and withdrawal of the rejection under 35 U.S.C. §103 is respectfully requested.

### **CONCLUSION**

Based on the foregoing amendment and remarks, applicants respectfully submit that the claims as currently presented are patentable and in condition for allowance.

If any issues remain, or if the Examiner has any suggestions for expediting allowance of this application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Favorable consideration is respectfully requested.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees that may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 4303-4005. **A DUPLICATE OF THIS DOCUMENT IS ATTACHED.**

Respectfully submitted,

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